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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,344	04/04/2008	Lawrence Solomon	SLP-036	2815

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EXAMINER	
LOVE, TREVOR M	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
05/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,344	SOLOMON ET AL.	
	Examiner	Art Unit	
	TREVOR M. LOVE	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04/17/2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made to Applicant's response filed 04/17/2009.

Claims 1-13 are currently pending and under consideration.

Any rejections or objections of record not set forth herein are to be considered withdrawn.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lieberman, Herbert (Pharmaceutical Dosage Forms – tablets, 1990) in view Geller, Ehud (U.S. Patent number 3,927,194).

Leiberman, in section "IV. Layer Tablets" first paragraph, discloses layered tablets wherein the layers are "sandwiched" on top of each other, and the edges are exposed (such as instant claim 3). Said layered tablets are disclosed as 2 or 3 layers of granulation compressed together. Leiberman teaches that layered dosage forms have the advantage of being able to separate two incompatible substances with an inert barrier (such as instant claim 5), or instead of modifying the active ingredient, they can be used to modify the release profile, each layer can comprise components that determine either immediate, intermediate, or slow release of the active. Furthermore, Leiberman discloses that the layered tablet method allows for the weight of each layer to be accurately modified. The multilayer tablets are also disclosed as being capable of having "distinctive markings" impressed on the surface. Leiberman, in the section

discussing the "Properties of Tablets" discloses under point "4" that tablets can contain markings. Said markings may appear as a score or crease across the face, which is intended to permit breaking the tablet into equal parts for administration. Leiberman, however, states that substantial variation can occur in manually broken tablets.

Leiberman fails to directly envisage that the score on the multilayer tablet extends at least 70% of the distance of the first segment of said multilayer tablet.

Geller teaches a tablet which is scored sufficiently to form a groove which is 1/3 to 2/3 the depth of the total tablet thickness. This groove being designed to facilitate separation into subdivisions containing substantially equal amounts of pharmaceutically active ingredients (see claim 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the groove of Geller in the tablets of Leiberman. One would have been motivated to do so to allow for easy, simple, and accurate division of a pharmaceutical tablet (see Geller, column 1, lines 12-14). There would be a reasonable expectation of success since both Leiberman and Geller teach that tablets can be scored in order to facilitate breaking the tablet into equal parts for administration.

With regard to claims 1, 2 and 10, it would have been obvious to one of ordinary skill in the art to optimize the thickness of each layer; this is directly taught by Leiberman (see page 274, section IV, first paragraph). One would have been motivated to do so to minimize the amount of the first layer that was involved in the breaking of the tablet with the intent of reducing the variability in the concentration of the components of the top layer.

With regard to claim 3, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have all three layers be directly atop one another. One would have been motivated to do so since Leiberman teaches a two or three layer composition wherein the components have the appearance of a sandwich because the edges of each layer are exposed (see page 274, section IV first paragraph).

With regard to claims 4-7, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the contents of the different layers. One would have been motivated to use different actives in the different layers since Leiberman teaches one motivation for layering is the separation of incompatible layers, which would obviously contain different substances, and would comprise at least three layers in order to achieve effective separation (see page 274, section IV, first paragraph). In the same paragraph Leiberman teaches that another motivation for layering is varying the speed of release of the different coatings. Leiberman directly teaches three coatings, all with different release rates: immediate, slow release, and intermediate release.

With regard to claim 12, it would have been obvious to one of ordinary skill in the art at the time the invention was made to divide the tablet to allow for smaller doses of the active ingredients. One would have been motivated to do so since Leiberman directly teaches the use of scoring “to permit breaking the tablet into equal parts for the administration of half a tablet” (see page 132, section I, point 4). It would be obvious to administer a smaller dose portion of a tablet to a patient in need there of.

With regard to claim 13, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize drugs directed towards the treatment of cardiovascular conditions. One would have been motivated to do so since Geller discloses that the scoring method taught in Geller is "directed principally to the application of specific pharmaceutical formulations incorporating isosorbide dinitrate as the active ingredient", but is applicable to other actives as well. Isosorbide dinitrate being a potent coronary vasodilator (see column 2, lines 28-33).

Applicant's Arguments

Applicant argues in the response filed 04/17/2009 that while Applicant agrees that Lieberman discloses the concept of scoring a pharmaceutical, Applicant believes that Lieberman fails to teach a scored tablet with two segments, one of which has no active ingredient or a tablet where the score extends at least 70% of the distance to the second segment (see remarks, last paragraph, page marked 5). Applicant further argues that Geller fails to disclose a concept of providing equal amounts of pharmaceutically active ingredients when a scored tablet is broken along the score (see remarks, first paragraph, page marked 6). Applicant further argues that there is no reason to modify Lieberman with the scoring technique of Geller. Further, Applicant argues that Lieberman and Geller, alone or in combination, do not teach the concept of claim 8 which would cause all or most of the breakage to occur in an inert layer. Applicant argues that the differences in breaking a layered verses an unlayered tablet point to unobviousness of the claimed invention.

Response to Arguments

Applicant's arguments have been fully considered and are not found persuasive. As identified above, Lieberman and Geller provide sufficient teaching and motivation to arrive at the instantly claimed invention. For instance, Lieberman teaches the benefits of a layered tablet, along with the advantages and uses of a multilayered tablet. Lieberman further provides motivation for the multiple layers to comprise different components, whether that be different actives or inert components. Furthermore, Geller teaches the advantage of utilizing a deep score which allows for the composition to be broken more efficiently and causes smaller amounts of deviation to occur in dosing. As for Applicant's argument that there is insufficient motivation to modify Lieberman with the scoring technique of Geller, Geller directly teaches that the utilization of the scoring method of Geller provides easy, simple, and accurate division of a pharmaceutical tablet (see Geller, column 1, lines 12-14). Applicant's argument that Lieberman and Geller, alone or in combination, fail to teach that the majority of said breakage occurs in an inert layer is not found persuasive since Lieberman teaches a multilayer tablet wherein said layers can be either active containing or inert. Specifically, it would have been obvious to one of ordinary skill in the art to desire said breakage to occur at least mostly in an inert layer to allow for more accurate divisions, which is a well known desired feature, as shown by Geller.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-7, and 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-11, 13-18, of copending Application No. 11/441455 .

Although the conflicting claims are not identical, they are not patentably distinct from each other because application ‘455 anticipates the product of the instant claims by disclosing a an immediate release partial dose of a drug contained in a segmented dosage form by breaking a tablet through a score, wherein a first segment contains a drug, and a second segment can either contain a drug or be drug free, comprising a score at least 50%, and preferably 70%, through said first segment (claims 2, 3, 5, 6, 13, 14, 15, 16, 17, and 18 read on instant claims 1 and 10). ’455 also discloses a method wherein the tablet contains a third layer, said third layer being adjoined at a face of said second segment opposite the interface of said first and second segments wherein said third segment contains the same drug as the first segment (claims 7, 8,

and 9 read on instant claims 5, 3, and 4, respectively, claim 19 also reads on claim 3). Furthermore, '455 discloses that the second segment can contain different drugs from those contained in the first segment, or that the second segment can contain the same drug as the first segment, but in a different weight ratio (claims 10 and 11 read on instant claims 6 and 7, respectively).

This rejection is anticipatory because application '455 teaches a method of using a composition, and said composition is described as being the composition of the instant claims. The method therefore anticipates the product.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

It is noted that Applicant failed to traverse or set forth arguments with regard to the nonstatutory obviousness-type double patenting rejection of record. As such, the rejection is maintained.

Conclusion

No claims allowed. All claims rejected. No claims objected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611